K070516

510(k) Summary

As required by section 807.92(c)

JUL - 2 2007

Submitted by:

PowerMedic ApS
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Contact Person: Arne Grinsted

Prepared On: Monday, January 08, 2007

Classification Name: Lamp, Infrared

Common Name: Infrared Laser

Proprietary Name: PowerLaser

Classification: The device satisfies the 21 CFR definition of a Class II infrared lamp as follows:

Regulation Number	Classification Number	Product Nomenclature	Identification / Classification
890.5500	ILY	Lamp, Infrared	A device that emits energy at infrared frequencies (approximately 700 nanometers) to 50,000 nanometers to provide topical heating

Establishment registration: Owner / Operator No.: 9052408.

US Representative: PowerMedic US Inc.

Development: PowerMedic ApS has developed the device.

Production: PowerMedic ApS is manufacturing and packaging the device.

Reason for the 510(k): The Product has never been marketed in USA before. However the PowerLaser 90 has been marketed in the USA since 2003.

Substantial Equivalence:	The PowerLaser is substantially equivalent to other infrared lamps currently in commercial distribution such as the PowerLaser 90 which was the subject of 510(k) number K030692 and the Vectra Genisys Laser System which was the subject of 510(k) number K040662. The PowerLaser has the equivalent intended use (i.e. pain relief).
Device Description:	The PowerLaser is a hand-held, battery operated, non-invasive, low level infrared therapeutic laser lamp. A separate battery charger can recharge the battery when it is removed from the PowerLaser. PowerLaser is a medical device, which is delivered packed with battery charger and complete labeling for the user.
Special Controls:	The PowerLaser as well as the battery charger demonstrates compliance to relevant safety-standards, EMC standards and standards for low level infrared laser equipment.
Statement of Indications for use:	The PowerLaser is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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% Arne Grinsted
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Re: K070516
Trade/Device Name: PowerLaser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: February 8, 2007
Received: February 13, 2007

Dear Arne Grinsted:

This letter corrects our substantially equivalent letter of July 2, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

POWER MEDIC
HEALING TECHNOLOGY

Indications for Use

510(k) Number (if known): 070516

Device Name: PowerLaser

Indications for Use:

The PowerLaser is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; the temporary relaxation of muscle and/or increased healing of wounds.

Prescription Use: X (Part 21 CFR 801 Subpart D)	**AND/OR**	**Over-The-Counter Use:_____ (21 CFR 801 Subpart C)**

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k070516